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09/508,745	07/12/2000	SUZANNE CORY	13464	7536

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EXAMINER

BERTOGLIO, VALARIE E

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

814

Office Action Summary

Application No.

09/508,745

Applicant(s)

CORY ET AL.

Examiner

Valarie Bertoglio

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 4-8, 10 and 11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 9 and 12-20 is/are rejected.
- 7) ☒ Claim(s) 1-3, 9 and 12-20 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 March 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>01/02</u> | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1632

DETAILED ACTION

Claims 1-20 are pending.

Election/Restrictions

Applicant's election with traverse of Group III, claims 1-3,9, and 12-20, in the election received 01/02/2004 is acknowledged. Applicant's arguments are not found persuasive because the claimed subject matter is drawn to multiple, different animals that require different methods to make and use the animals. Because the groups are drawn to genetically different animals made through entirely different mechanisms, they do not represent multiple aspects of a single invention as argued by Applicant. Furthermore, there is no shared or corresponding special technical feature among the inventions. The technical feature of Groups I-III is reduction of Bcl-w protein through non-transgenic mechanisms. The technical feature of Groups IV and V a Bcl-w associated protein. Bcl-w is not a contribution over the prior art as the bcl-w gene was described by Gibson (1996, Oncogene, Vol. 13, pages 665-675), which was published before the effective filing date of the instant application of 09/16/1997. The requirement is still deemed proper and is therefore made FINAL.

Claims 4-8, 10 and 11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the election received 01/02/2004. Claims 1-3,9 and 12-20 are under consideration in the instant office action.

Specification

The disclosure is objected to because of the following informalities: In the Description of the Figures (pages 6-7), figure descriptions should contain a heading for each figure described in

Art Unit: 1632

a paragraph. For example, page 6, line 2 should begin "Figures 1A-1F"; page 6, line 17 should begin "Figures 2A-2C".

Appropriate correction is required.

Claim Objections

Claims 1-3,9,14-20 are objected to as containing subject matter drawn to a non-elected invention.

Claim 20 is objected to because of the following informalities: The word "stringency" is misspelled (line 5). Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-3,9,12,13 and 18-20 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims encompass any animal species, including humans, and more specifically, transgenic humans. Furthermore, claim 19 limits the bcl-w mutation to chromosome 14q11, which is the chromosomal map location of the human bcl-w gene. A human being is non-statutory subject matter. See 1077 O.G. 24, April 21, 1987.

Claim Rejections - 35 USC § 112-1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

Art Unit: 1632

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3,9 and 12-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116).

The specification has described the nucleotide sequence set forth by SEQ ID NO:3 and the nucleotide sequence encoding the amino acid sequence set forth in SEQ ID NO:4. The specification, however, has not described any variant sequences of the nucleotide sequence set forth in SEQ ID NO:3 or of the nucleotide sequence encoding the amino acid sequence set forth in SEQ ID NO:4 that are within the genus wherein such variants include nucleotide sequences having at least 47% similarity to the nucleotide sequence set forth in SEQ ID NO:3, nucleotide sequences encoding amino acid sequences having at least 47% similarity to the amino acid sequence set forth in SEQ ID NO:4, any nucleotide sequence capable of hybridizing to the nucleotide sequence set forth in SEQ ID NO:3 and any nucleotide sequence encoding Bcl-w.

Art Unit: 1632

In the instant case the Bcl-w variants encompassed by the claims lack a written description. The specification fails to describe what DNA molecules fall into this genus and it was unknown as of Applicants' effective filing date that any of these DNA molecules would have the property of encoding the Bcl-w polypeptide having the same structural and functional properties as that encoded by SEQ ID NO:3. The claimed embodiments of Bcl-w variants encompassed within the genus lack a written description. There is no evidence on the record of a relationship between the structures of the nucleotide sequences coding for the Bcl-w variants and the nucleotide sequence set forth by SEQ ID NO:3 or the Bcl-w variants and the polypeptide sequence set forth by SEQ ID NO:4 that would provide any reliable information about the structure of DNA molecules within the genus. The claimed invention as a whole is not adequately described if the claims require essential or critical elements that are not adequately described in the specification and that is not conventional in the art as of applicants effective filing date. Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. Pfaff v. Wells Electronics, Inc., 48 USPQ2d 1641,1646 (1998).

With the exception of the sequence referred to above, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides or polypeptides, and therefore conception is not achieved until reduction to practice has occurred regardless of the complexity or simplicity of the method of isolation. The skilled artisan cannot envision the detailed chemical structure of the encompassed nucleic acid molecules and therefore conception

Art Unit: 1632

is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The nucleic acid itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

In view of the above considerations one of skill in the art would not recognize that applicant was in possession of the necessary common features or attributes possessed by any member of the genus of Bcl-1 variants encompassed by the claims. Therefore, only the Bcl-w gene encompassed by SEQ ID NO:3 and the corresponding polypeptide encompassed by SEQ ID NO:4, but not the full breadth of the claims meet the written description provision of 35 U.S.C. §112, first paragraph. University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that "to fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude "the inventor invented the claimed invention".

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Art Unit: 1632

1) The claims embrace all species of transgenic animals and birds, including male and female animals or birds. However, the specification has only taught generating transgenic mice comprising a targeted gene disruption of the *bcl-w* gene set forth by SEQ ID NO:3 (page 18, lines 20-23). The art at the time of filing held that targeted gene insertion technology was not available for any species other than mouse. Since homologous recombination is required for gene targeting methods, cells in culture must be used for the gene-targeting event. The only cells in culture known to give rise to the germ-line, and are therefore capable of generating a transgenic animal whose genome comprises a targeted gene disruption, are mouse ES cells. Campbell and Wilmot (1997, *Theriogenology*, vol. 47, pp, 63-72) acknowledge reports of ES-like cells in a number of species, but emphasize that as yet there are no reports of any cells lines that contribute to the germ line in any species other than mouse (page 65). Lederman also highlights the fact that germ-line competent ES cell lines from species other than mouse have not been isolate (2000, *Experimental Physiology*, Vol. 85, pages 603-613, specifically, page 604, column 1, lines 7-8). The specification does not teach any totipotent ES cells other than mouse ES cells. It would require undue experimentation for the skilled artisan to determine how to isolate totipotent ES cells from species other than mouse and to generate an animal or avian species with a targeted gene disruption.

2) The claims embrace both male and female mice comprising either a heterozygous or homozygous disruption of the *bcl-w* gene, or variants thereof, wherein the mice exhibit either reduced or incapacity for spermatogenesis (claims 1-3,9, and 18-20; see page 24, lines 6-10) or any phenotype (claims 12-17). Claims 18 and 19 are limited to male mice. However, the specification has only taught generating homozygous male mice comprising a disruption of the

Art Unit: 1632

bcl-w set forth by SEQ ID NO:3 exhibiting incapacity for spermatogenesis and has not taught any other animal or avian species encompassed by the claims. The specification has not taught disruption of any gene other than that set forth by SQ ID NO:3. The specification has not taught any phenotype for any mouse other than homozygous males and has not taught any phenotype other than incapacity for spermatogenesis for the homozygous males. Specifically, the specification has not taught a reduced capacity for spermatogenesis, but an incapacity as the mice were “devoid of sperm” (page 24, line 8).

The art at the time of filing held that the phenotype of transgenic knockout mice was unpredictable (Moreadith et al., 1997, J. Mol. Med., Vol. 75, pages 208-216, see page 208, column 2, last full paragraph). Moens et al. (Development, Vol. 119, pages 485-499, 1993) disclose that two mutations produced by homologous recombination in two different locations of the N-myc gene produce two different phenotypes in mouse embryonic stem cells, one leaky and one null (see abstract). Furthermore, Leonard (1995, Immunological Reviews, Vol. 148, pages 98-113) disclosed mice with a disruption in the g_c gene that was intended to be a model for X-linked severe combined immunodeficiency (XSCID), but display a variety of unexpected traits (abstract). These knockout mice were expected to have thymocytes with decreased proliferation in response to stimulation with antibodies, but the thymocytes proliferated normally (page 105, line 7). Finally, Griffiths (1998, Microscopy Research and Technique, Vol. 41, pages 344-358) taught that, despite a known role for the PLP gene based on spontaneous mutations in the gene, the knockout mouse failed to display any of the expected phenotypes (page 350, last paragraph).

Because the phenotype of a knockout mouse is unpredictable, one cannot guess what the phenotype of the animals of claims 12-17 might be and one cannot determine, a priori, how to

Art Unit: 1632

generate the claimed animal such that it has any particular phenotype. Furthermore, without a recitation of a phenotype in the claim, one would not know when they had attained the claimed animal (for claims 12-17). With respect to claims 1-3 and 20, one of skill in the art would not know how to generate a female mouse with a reduced capacity (or incapacity) for spermatogenesis because females do not carry out spermatogenesis. With respect to the heterozygous animals encompassed by the claims, the specification fails to provide any teachings with respect to the phenotype of heterozygotes and the phenotype is unpredictable. With respect to the bcl-w variants encompassed by the claims, the specification fails to provide the guidance necessary to disrupt any bcl-w variant other than the bcl-w gene set forth by SEQ ID NO:3 such that any specific phenotype is obtained. Therefore, in light of the unpredictability of phenotype in transgenic animals as set forth by the state of the art, it would require one of skill in the art at the time the invention was made, undue experimentation to determine how to generate the claimed heterozygous animals with any phenotype, the claimed female animals with any phenotype and the claimed homozygous male animals with any phenotype other than an incapacity for spermatogenesis.

3) The claims embrace animals and birds exhibiting reduced levels of a Bcl-w protein that is caused by means other than targeted-gene disruption wherein the disruption results in a null allele by removal or disruption of the 5' end of the coding region. The claims encompass any type of genetic modification of the bcl-w gene set forth by SEQ ID NO:3. The specification has taught replacing the first 413 bp of the bcl-w coding region with PGK-neo^r (page 6, lines 9-10; Figure 1). Subsequent removal of PGK-neo^r, resulting in a deletion of the 5' end of the bcl-w gene, failed to alter the phenotype of the mouse (page 22, lines 17-28). Either disruption, when

Art Unit: 1632

homozygous, would result in the failure to produce any wild-type Bcl-w protein. The specification has not taught how to reduce the level of Bcl-w to any level other than a total lack of wild-type protein such that a desirable phenotype (incapacity for spermatogenesis) is obtained. Furthermore, the specification has not taught any other genetic modification that results in reduced levels of Bcl-w protein in a homozygous animal. For example, the skilled artisan would not know which specific nucleotides within the bcl-w gene to alter or how much of the gene to delete to obtain an allele that results in reduced or incapacity for spermatogenesis or any other phenotype. The specification does not provide the guidance necessary to alter specific nucleotides of the bcl-w gene or to make insertions or deletions other than at the 5' end such that bcl-w expression is altered and any specific phenotype is obtained. Other than a targeted 5' gene deletion or insertion that disrupts all bcl-w function, the specification fails to provide the guidance necessary to generate any modification in the bcl-w gene such that reduced levels of Bcl-w protein occurs and a useful and desirable phenotype results. Animals heterozygous for a null allele of bcl-w would be expected to exhibit reduced levels of a Bcl-w protein, however, a phenotype for this animal was not provided by the instant specification.

4) Claims 1-3,9 and 12-20 embrace chimeric mice (genetic mosaics) wherein only a portion of the cells of the mouse comprises the claimed genetic disruption. Claim 14 is directed specifically to a chimeric animal. The specification has taught transgenic male mice whose somatic and germ cells all comprise a homozygous targeted disruption of the bcl-w gene wherein the mice exhibit incapacity for spermatogenesis. The specification has failed provide the guidance necessary to make chimeric mice such that they exhibit any phenotype, including

Art Unit: 1632

incapacity or reduced capacity for spermatogenesis, and fails to enable using the chimeric mice exhibiting any phenotype encompassed by the claims.

The method of making genetic mosaic animals is such that each resulting chimera is comprised of a different, unpredictable ratio of cells of various genotypes. This ratio cannot be predetermined. Furthermore, the spatial distribution of cells of each genotype cannot be predetermined. Therefore, the phenotype of chimeric animals is not only dependent upon the genotype of the cells (which is unpredictable as set forth by the state of the art outlined above; for example see Leonard; Griffiths) but is also dependent upon the spatial distribution of the cells and their relative population size. Thus, the phenotype of the chimeric animals encompassed by the claims is highly unpredictable. It would require undue experimentation for one of skill in the art to determine how to overcome the unpredictability associated with making chimeric animals such that the proportion and population of cells harboring a genetic alteration could be controlled in such a way as to increase the predictability of the phenotype of the resulting chimeric animal.

5) The claims embrace animal or avian species exhibiting reduced capacity for spermatogenesis. The specification has taught that homozygous mice comprising a disruption of the *bcl-w* gene fail to produce any sperm (page 24, line 8). The specification has not taught how to alter the *bcl-w* gene such that any reduction in spermatogenesis other than a complete reduction is achieved such that an incapacity for spermatogenesis is achieved. Due to the unpredictability of phenotype in transgenic animals as set forth above, it would require undue experimentation to determine how to alter the *bcl-w* gene in a manner to cause reduced levels of Bcl-w resulting in reduced levels of spermatogenesis.

Art Unit: 1632

6) The specification fails to enable claim 18, which is drawn to any species of animal comprising a mutation on chromosome 14q11. 14q11 is the location of the human bcl-w gene. Not all species of animals contain the bcl-w gene at 14q11 because not all animals have a chromosome 14. Furthermore, the mouse bcl-w is located on the middle of chromosome 14, not at “14q11” (Gibson, 1996, page 669, col. 2, paragraphs 2 and 3). Therefore, one of skill in the art would not know how to alter the bcl-w gene at 14q11 of any species of animal other than human.

Therefore, in view of the quantity of experimentation necessary to determine the parameters listed above, the lack of direction and/or guidance provided by the specification, the underdeveloped art with respect to ES cell technology, the unpredictability of phenotype of transgenic animals, and the breadth of the claims with respect to the animal and avian species and bcl-w variants, it would have required undue experimentation for one skilled in the art to make and use the claimed invention with a reasonable expectation of success.

Claim Rejections - 35 USC § 112-2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3,9 and 12-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The use of the term “and/or” renders claim 1 unclear (line 2). It is unclear whether the claim is encompassing reduced levels of either a single or multiple proteins. Claim 2,3 and 9 depend from claim 1.

Art Unit: 1632

The phrase “a Bcl-w protein and/or protein associated with Bcl-w or a derivative or homologue thereof” (line 2) renders claim 1 unclear. It is unclear whether the “derivative or homologue thereof” is referring to the Bcl-1 protein or the protein associated with Bcl-w or both. Claims 2,3 and 9 depend from claim 1.

The phrase “said animal or avian species has an incapacity or a reduced capacity to induce or facilitate spermatogenesis” renders claim 1 unclear. It is not clear how an animal induces or facilitates spermatogenesis. A protein may facilitate spermatogenesis; an animal does not. Furthermore, it is not clear what is encompassed by the phrase “induce or facilitate”. It is not clear how spermatogenesis can be facilitated. The specification fails to define the terms “induce” or “facilitate” and the link between bcl-w and induction of spermatogenesis is unclear. Claims 2,3 and 9 depend from claim 1.

The term "reduced capacity" in claim 1, line 3 is a relative term, which renders the claim indefinite. The term " reduced capacity " is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Claims 2,3 and 9 depend from claim 1.

Claims 2,3,12 are unclear because it uses the terminology “at least about”. It is unclear what this phrase encompasses. It is unclear if it encompass an amount near 47% or greater than 47%. It is unclear how much more than 47% would be encompassed by the claim. Claim 9 depends form claims 2 and 3 and is included in this rejection. Claim 13 depends from claim 12.

The phrase "capable of hybridizing" in claim 3, line 4, in claim 12, line 4 and in claim 20, line 4 is a relative phrase that renders the claim indefinite. The phrase "capable of hybridizing" is not defined by the claim, the specification does not provide a standard for ascertaining the

Art Unit: 1632

requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Claim 9 depends from claim 3 and is included in this rejection. Claim 13 depends from claim 12.

Claim 3 is unclear because it claims "a nucleotide sequence having at least about 47% similarity thereto". Nucleotides can share identity, not similarity. Only peptides share similarity.

The use of the term "and/or" renders claim 12 unclear (line 3). It is unclear whether the claim is encompassing a sequence having similarity to SEQ ID NO:3 or a sequence capable of hybridizing to SEQ ID NO:3 or both. Claim 13 depends from claim 12.

The term "substantially " in claim 3, line 2, in claim 12, line 2, in claim 14, line 1, and in claim 20, lines 2 and 3 is a relative phrase that renders the claim indefinite. The term "substantially " is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Claims 15-17 depend from claim 12 and are included in this rejection. Claim 9 depends from claim 3 and is included in this rejection. Claim 13 depends from claim 12 and is included in this rejection. Claims 15-17 depend from claim.

Claim 16 is unclear. The claim states "wherein the introduced genetic sequence is an antisense molecule, encoding an antisense molecule" (lines 1-2). It is not clear how an antisense molecule can encode an antisense molecule. Claim 17 depends from claim 16.

Claim 17 recites the limitation "the Cre recombinase" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 17 is unclear. Claim 17 depends from claim 14, which is drawn to introducing a genetic sequence that the bcl-w gene. Claim 17 limits the introduced genetic sequence to that

Art Unit: 1632

encoding Cre recombinase. This is inconsistent with the specification where the introduced genetic sequence is PGK-neo^r flanked by loxP sites (page 22, lines 6-7). Cre was introduced through mating with a mouse comprising the Cre transgene. It is unclear, based on the teachings in the specification if the Cre recombinase gene of claim 17 is part of the gene introduced into the bcl-w gene or is a second, independent genetic sequence as described in the specification.

The phrase “comprising a mutation in a gene corresponding to bcl-w” renders claims 18 unclear (line 1). It is unclear whether it the mutation or the gene corresponds to bcl-w). Claim 19 depends from claim 18.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is (571) 272-0725. The examiner can normally be reached on Mon-Fri 6:00-2:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

**PETER PARAS, JR.
PRIMARY EXAMINER**

